DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAY 21 1997

Re: BeneFIX™
Docket No. 97E-0168

Stephen G. Kunin
Deputy Assistant Commissioner for
Patent Policy and Projects
U.S. Patent and Trademark Office
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Mr. Kunin:

This is in regard to the application for patent term extension for U.S. Patent No. 5,171,569 filed by British Technology Group Limited under 35 U.S.C. § 156. The human drug product claimed by the patent is BeneFIX™ (Coagulation Factor IX (Recombinant)), which was assigned Product License Application (PLA) No. 96-1048.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). Our records also indicate that it represents the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1), and interpreted by the courts in Glaxo Operations UK Ltd. v. Quigg, 706 F. Supp. 1224 (E.D. Va. 1989), aff'd, 894 F. 2d 392 (Fed. Cir. 1990).

The PLA was approved on February 11, 1997, which makes the submission of the patent term extension application on March 6, 1997, timely within the meaning of 35 U.S.C. § 156(d)(1).

In your March 20, 1997 letter to FDA, your Legal Advisor for this issue, Karin Tyson, requested that FDA provide "a copy of any parts of the IND or Biologics License Application which describe what rFIX [BeneFIX™] is or how it is made." Pursuant a telephone conversation with Ms. Tyson on May 13, 1997, Brian Malkin, Associate Director for Patents and Hearings, explained to Ms. Tyson that currently there was no public information on BeneFIX™ that could be released. Mr. Malkin further explained that for FDA to release the commerical confidential information that Ms. Tyson referred to, special arrangements would have to be made regarding transfer of the information for the purpose of determining eligibility of the product for patent term extension. Ms. Tyson said that because the same information was requested from the patent extension applicant, FDA should not respond to this part of the request for information at this time, but it may be required depending on the applicant's response.

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the Federal Register, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely,

Ronald L. Wilson

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs

cc: M. C. Meinert, Esq.
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